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PTO/SB/21 (08-08)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

7

Application Number

10/081,705

Filing Date

2/21/2002

First Named Inventor

Classen, John Barthelow

Art Unit

2161

Examiner Name

Leroux, Etienne Pierre

Attorney Docket Number

61185.00005

ENCLOSURES (Check all that apply)

☐

Fee Transmittal Form

☐

Fee Attached

☒

Amendment/Reply

☐

After Final

☒

Affidavits/declaration(s)

☐

Extension of Time Request

☐

Express Abandonment Request

☐

Information Disclosure Statement

☐

Certified Copy of Priority Document(s)

☐

Reply to Missing Parts/
Incomplete Application

☐

Reply to Missing Parts
under 37 CFR 1.52 or 1.53

☐

Drawing(s)

☐

Licensing-related Papers

☐

Petition

☐

Petition to Convert to a
Provisional Application

☐

Power of Attorney, Revocation

☐

Change of Correspondence Address

☐

Terminal Disclaimer

☐

Request for Refund

☐

CD, Number of CD(s) _____

☐ Landscape Table on CD

Remarks

☐

After Allowance Communication to TC

☐

Appeal Communication to Board
of Appeals and Interferences

☐

Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)

☐

Proprietary Information

☐

Status Letter

☒

Other Enclosure(s) (please identify
below):

- Return Postcard

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Montgomery, McCracken, Walker & Rhoads, LLP

Signature

Evelyn H. McConathy

Printed name

Evelyn H. McConathy

Date

9/23/2008

Reg. No.

35,279

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature

James L. Cannon II

Typed or printed name

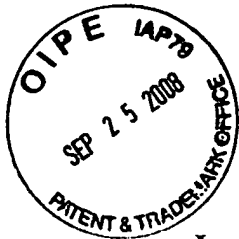
James L. Cannon II

Date

9/23/2008

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow Classen

Attorney Docket: 61185.00005

Application No.: 10/081,705

Group Art Unit: 1273

Filed: 02/21/2002

Examiner: LEROUX, Etienne Pierre

Title: *Computer Algorithms and Methods for Product Safety*

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMUNICATION RE EXECUTED LETTER
FROM JOHN BARTHELOW CLASSEN

Sir:

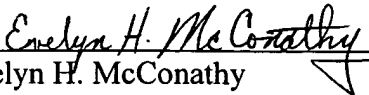
Enclosed please find the executed letter from John Barthelow Classen dated for November 12, 2000 that was previously submitted by Applicant unsigned as an attachment of the Declaration of John Barthelow Classen Under 37 C.F.R. §1.131, (attached hereto as filed for the Examiner's convenience) filed with the Applicant's Reply To Examiner's Answer Re Appeal on August 1, 2008 describing methods and systems for developing proprietary safety information pertaining to medical products. Please enter this letter with Applicant's Reply to replace the unsigned attachment filed in the Reply mailed on August 14, 2008.

No additional fee is believed to be due in this filing. However, in the event that an additional fee or any other fee is required, Applicant hereby authorizes the Commissioner to charge any necessary fees to deposit account No. 50-2424. Should the Board have any questions prior to oral hearing, it is encouraged to contact Applicant's undersigned representative at (215) 772-7550.

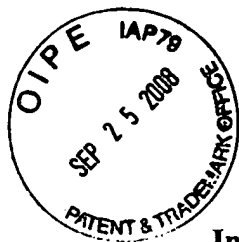
Respectfully submitted,

Dated: September 23, 2008

By:



Evelyn H. McConathy
Registration No. 35,279
Attorney for Applicants
MONTGOMERY, McCracken,
WALKER & RHOADS, LLP
123 South Broad Street
Philadelphia, PA 19109-1099
Tel: (215) 772.7550
Fax: (215) 772.7620



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Barthelow Classen

Attorney Docket: 61185.00005

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Declaration of John Barthelow Classen under 37 C.F.R. §1.131

I, John Barthelow Classen declare that:

1. I am the sole named and true inventor of U.S. Patent Appl. 10/081,705, filed February 21, 2002, claiming an effective filing date of February 21, 2001, when U.S. Provisional Application No. 60/270,697 was filed, the content of which was incorporated into the present application in its entirety.
2. The United States of America is the only country in the world that has a "first to invent" law. All other countries use "first to file" laws where the first party to file a patent application on a new invention will generally be the one that gets the patent. In the United States the assertion that one is "first to invent" must be supported by solid, verifiable records of the date of invention, followed by diligent pursuit. Verifiable records may be by: 1) records that are understood and witnessed by unbiased third parties that can and will testify about them in court, 2) contemporaneously prepared (or collected) business records that are believable and that you (or their preparers) can believably swear by, and 3) records that are held by an unimpeachable source (such as the now-ended disclosure program at the U.S. PTO).
3. The Patent Examiner has cited U.S. Published Patent Application 2002/0039990 by Stanton, filed December 7, 2000, published April 4, 2002 as prior art under §103(a) against the patentability of my claimed invention.
4. As I understand it, 35 U.S.C. §103(a) states that "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title." In turning to 35 U.S.C. §102(e), an Applicant is entitled to a patent unless the invention was "(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent.

5. However, 35 U.S.C. §102(e), would not apply to my invention as compared to Stanton for the purpose of establishing a priority date. Only section of 35 U.S.C. §102(e)(1) is relevant to the present situation, and section (1) specifies the publication of the application. As I have repeatedly explained, Stanton is not an application for patent that was *published* by another in the US *before Applicant's actual invention*. Stanton was not published until April 4, 2002, well *AFTER* my constructive date of invention based upon the effective filing February 21, 2001. Consequently, Stanton is not proper prior art as applied to my invention.

6. Moreover, since 35 U.S.C. §102(e) applies to my actual date of invention, I have submitted several documents to the U.S. Patent Office to establish my actual date of invention, which was well before even the December 7, 2000 filing date of the Stanton application. These letters, although submitted to the Patent Office in 1999 and 2000, under the "disclosure" option at the PTO discussed as option (3) above (which was discontinued in February 2007) have not been considered by the Examiner in this case. The disclosure program was established by the Patent Office for exactly this purpose, to permit inventors to place their inventions on record until a formal application could be filed. See link at <http://www.uspto.gov/web/offices/pac/disdo.html>.

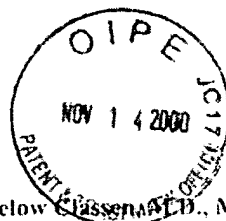
7. Attached are copies of letters submitted to Box DD of the U.S. PTO on July 25, 1999 and November 12, 2000, describing my conception of improvements to my earlier filed patent application, USSN 09/449,178, filed Nov. 24, 1999, now U.S. Pat. No. 6,219,674. These letters (presently in unsigned form, which will be followed by copies of the signed letters), clearly demonstrate that my actual date of invention antedates the December 7, 2000 filing date of the Stanton application, as well as my continued diligence. Copies of these letters are also available to the Examiner at the PTO wherever records of the disclosure program are maintained. Moreover, ongoing meetings were held with my attorneys *prior to December 7, 2000*, wherein filing of provisional application 60/270,697 (filed very shortly thereafter), and the content thereof were discussed.

8. Consequently, Stanton is not proper prior art against my present invention, since the actual date of my invention is shown to have preceded the filing date of Stanton's cited published patent application.

9. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: August 1, 2008

John Barthelow Classen



J. Barthelow Classen, M.B.A.
Classen Immunotherapies
6517 Montrose Avenue
Baltimore, MD 21212
Tel: (410) 377-4549 Fax: (410) 377-8526
E mail: classen@vaccines.net http://vaccines.net

DISCLOSURE DOCUMENT NO.



482522

RETAINED FOR 2 YEARS

THIS IS NOT A PATENT APPLICATION

PTO-1852 (8/96)

November 12, 2000

Box DD
Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir or Madam:

I have submitted a patent application pertaining to business methods on or around November 24th, 1999. I have included a few improvements which I intend to patent where these improvements pertain to this invention.

1. The first invention pertains to comparing the incidence of the new adverse event to that in a control group where the control group received a competing technology. When the system is looking at a therapeutic modality such as a drug the improvement is using controls which receive an competing therapeutic modality such as a drug with treats the same disease or a surgical procedure that treats the same disease. If the system is looking at a fuel then the control group would be exposed to a competing fuel such as oil vs. coal vs. natural gas versus electricity. In the like manner the system could compare those exposed to a oil based paint to a latex based paint as a non limiting example.

2. An related improvement is that the manufacturer, distributor or marketer of a product could include a licensing agreement with the sale of the product which states the product can only be used for certain purposes. The license would exclude the use of the product to determine new proprietary uses, where the new uses are discovered by looking for new adverse events. The licensing agreement could be similar to that seen with software where the breaking of a seal indicates one agrees with the contract. The licensing agreement could accompany the product or alternatively could be signed prior to the delivery of a product to a purchaser, end user, distributor etc.

3. An related improvement is a claim that the system of the invention can not be used to try to discredit the existence of the one new adverse event, or the utility of the one new proprietary use. This will prevent competitors from trying to block the proprietary new use, product etc.

"The undersigned, being the inventor of the disclosed invention, requests that the enclosed papers be accepted under the Disclosure Document Program, and that they be preserved for a period of two years."

John B. Classen

